REMARKS

By way of the instant Preliminary Amendment, Applicants have rewritten claim 76 as an independent claim, and have incorporated the delineations of claims 1-2 from which claim 76 previously depended. Further, Applicants have canceled claims 1-20 and 77-78 without prejudice. Instead, Applicants have added claims 80-97, which depend on claim 76 and further delineate the feeder cells used in preparing the conditioned medium. Support for claims 80-97 is found in original claims 3-20. In addition, Applicants have added claims 98-100, directed to kits for deriving and culturing an ES cell line. The kits comprise the conditioned medium as characterized in claim 76 and a cell support matrix. Support for claims 98-100 is found in the specification, e.g., on page 27, lines 12-31. No new matter is introduced by the instant amendment.

In the Office Action dated May 3, 2006, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present application represents the following four separate and distinct inventions:

Group I Claims 1-20, drawn to a human feeder cell layer, classified in class 435, subclass 325, 363, 366, 371, for example.

Group II Claims 21-55, drawn to a method of deriving an ES cell line in a substantially undifferentiated state by obtaining an ES cell population and culturing the ES cells on a cell support matrix in the presence of soluble factors or equivalents thereof, classified in class 435, subclass 325, 363, 366, 371, 395, 401, 402 for example.

Group III. Claims 56-75, drawn to a culture system for deriving and culturing ES cells in a substantially undifferentiated state, said culture system including a cell support matrix, a cell culture medium for providing soluble factors derived from a human feeder cell, classified in class 435, subclass 325, 363, 366, 371, 377, 383, 384, 395, 401, 402.

Group IV Claims 76-79, drawn to a conditioned medium for deriving and culturing an ES cell line in an undifferentiated state, classified in class 325, subclass 404, 408.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group IV, claims 76-79, drawn to a conditioned medium for deriving and culturing an ES cell line in an undifferentiated state. Applicants respectfully direct the Examiner's attention to the fact that claims 77-78 have been canceled without prejudice, and claims 80-100 have been added. Specifically, claims 80-97, depending on claim 76, are also directed to condition media. Claims 98-100 are directed to kits which comprise the conditioned medium of claim 76. Therefore, Applicants respectfully submit that claims 80-100 should be examined together with claims 76 and 79. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application in the event that the Restriction Requirement is made final.

However, pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverses the Examiner's requirement for restriction and requests reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

Specifically, the Examiner contends that Groups I and IV are distinct products that are capable of separate use. The Examiner states that the human feeder cell layer of Group I does not need to be used to make conditioned medium, as human ES cells can grow directly on a human feeder layer. Furthermore, the Examiner states that the conditioned medium of Group IV can be used to culture other cell types.

Applicants respectfully submit that as presently recited, the conditioned media of Group IV (claims 76 and 79-97) are obtained by culturing the feeder cells of Group I. Clearly, the conditioned media of Group IV are related to the feeder cells of Group I. Further, the feeder cells of Group I and the conditioned media of Group IV share the function of supporting the derivation and culture of ES cells in a substantially undifferentiated state. Therefore, Applicants respectfully submit that Group I and Group IV are related to each other, and are not "independent and distinct".

The Examiner has also alleged that Group II and Group IV are mutually exclusive and independent. Specifically, the Examiner states that the methods of deriving an ES cell of Group II only require a cell support matrix and soluble factors from human feeder cells, but does not require the conditioned media of Group IV.

Applicants respectfully submit that it is believed that the conditioned media of Group IV contain soluble factors that support the derivation and culture of ES cells in a substantially undifferentiated state. Thus, the conditioned media of Group IV can be used in the methods of Group II. Certainly in this regard, Groups II and IV are related to each other.

Furthermore, the Examiner alleges that Groups III and IV are drawn to distinct products that can have separate use. Specifically, the Examiner contends that the culture system

of Group III can be used to culture other pluripotent cells in an undifferentiated state (such as PGCs, or embryonic germ cells).

Applicants respectfully submit that the culture system of Group III and the conditioned media of Group IV are specifically recognized by the present inventors to be suitable for the derivation and culture of ES cells in a substantially undifferentiated state. Therefore, Groups III and Group IV are related to each other in the context of the present invention.

Applicants further respectfully submit that Groups I-IV merely represent different aspects of a single invention. Notably, the courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade

and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs, or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicant respectfully urges the

Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined four groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims, or at least claims 76 and 79-100.

Respectfully submitted,

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